

Appl. No. 10/151,350
Reply to Office Action of November 18, 2003

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 102. (Canceled) Apparatus for implantation in a blood vessel that has a vessel wall, a vessel lumen defined by the vessel wall and an aneurysm formed in the vessel wall in communication with the vessel lumen, said apparatus comprising:

an intravascular member that has a collapsed configuration wherein it is in the form of an elongate strand member of a first diameter and an expanded configuration wherein the elongate strand member assumes a curved configuration which generally defines a tubular shape of a second diameter, said intravascular member being advanceable while in its collapsed configuration to a position within the lumen of the blood vessel adjacent to the aneurysm and then expandable to its expanded configuration wherein it engages the vessel wall and is thereby held in substantially fixed position within the vessel lumen adjacent to the aneurysm, and wherein the intravascular member defines a blood flow channel that permits blood to flow through the intravascular member while it is positioned in the blood vessel; and,

an embolus member that is transluminally advanceable through the lumen of the blood vessel and placeable within the aneurysm;
the intravascular member being operative to prevent the embolus member

Claim 103 (Canceled) Apparatus according to Claim 102 wherein the intravascular member self expands from its collapsed configuration to its expanded configuration.

Claim 104 (Canceled) Apparatus according to Claim 103 wherein the intravascular member self expands from its radially collapsed configuration to its radially expanded configuration.

Claim 105 (Canceled) Apparatus according to Claim 102 wherein the intravascular member comprises a helical coil when in its expanded configuration.

Claim 106 (Canceled) Apparatus according to Claim 102 wherein the intravascular member comprises an outer layer and an inner layer when in its expanded configuration.

Claim 107 (Canceled) Apparatus according to Claim 106 wherein the outer layer and the inner layer are formed of a continuous strand.

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Claim 108 (Canceled) Apparatus according to Claim 102 wherein the intravascular member is formed of a shape memory alloy.

Claim 109 (Canceled) Apparatus according to Claim 102 wherein the embolus member comprises a thrombogenic member.

Claim 110 (Canceled) A method for treating a mammalian patient who has a defect in the wall of a blood vessel that has a lumen and a wall, said method comprising the steps of:

- A. providing a first catheter that has a lumen extending therethrough, a second catheter that has a lumen extending therethrough, a third catheter that has a lumen extending therethrough and an intravascular member that is disposed within the lumen of the third catheter while in a collapsed configuration of a first diameter, said intravascular member being subsequently advanceable out of the lumen of the third
- B. placing the first catheter at a first position within the patient's vasculature;
- C. advancing the second catheter through the lumen of the first catheter and to a second position within the patient's vasculature;
- D. advancing the third catheter through the lumen of the second catheter to a third position within the patient's vasculature adjacent the vessel wall defect;
- E. while the first, second and third catheters are in their respective first, second and third positions, advancing the intravascular member out of the lumen of the third catheter such that the intravascular member assumes its radially expanded configuration and engages the wall of the blood vessel so as to be held in substantially fixed position within the vessel lumen adjacent to the vessel wall defect and so that it provides a blood flow channel to permit blood to flow past the intravascular member when it is positioned in the blood vessel;
- F. providing an embolus member sized to fit within the vessel wall defect; and,
- G. positioning the embolus member within the vessel wall defect such that the intravascular member retains the embolus member within the vessel wall defect.

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Claim 112 (Canceled) A method according to Claim 110 wherein Step E is performed after Step C.

Claim 113 (Canceled) A method according to Claim 112 wherein Step E comprises:

- i positioning a delivery catheter having a distal end within the intravascular member after it has been radially expanded in Step C;
- ii causing the distal end of the delivery catheter to advance through a portion of the intravascular member and into the vessel wall defect;
- iii delivering the embolus member out of the distal end of the delivery catheter and into the vessel wall defect; and,
- iv removing the delivery catheter, leaving the embolus member within the vessel wall defect with the intravascular member preventing the embolus member from escaping from the vessel wall defect into the lumen of the blood vessel.

Claim 114 (Canceled) A method according to Claim 113 wherein the intravascular member comprises a helical coil having a plurality of convolutions with spaces therebetween and wherein step ii comprises advancing the distal end of the delivery catheter through a space between two adjacent convolutions of the helical coil and into the vessel wall defect.

Claim 115 (Canceled) A method according to Claim 110 wherein the vessel wall defect is an aneurysm and wherein Step E comprises positioning the embolus member within the aneurysm.

Claim 116 (Canceled) A method according to Claim 115 wherein the aneurysm is a wide mouthed aneurysm and wherein Step E comprises delivering the embolus member through the mouth of the aneurysm and into the aneurysm sac.

Claim 117 (Canceled) A method according to Claim 115 wherein the aneurysm is a cerebral aneurysm.

Claim 118 (Canceled) A method according to Claim 110 wherein the embolic member delivered in Step E comprises a thrombogenic member.

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Claim 119 (Canceled) An intravascular flow modifier apparatus for treating a defect in a blood vessel wall into which blood flows from the lumen of the blood vessel, said apparatus comprising:

at least one biocompatible member that is initially disposable in a collapsed substantially linear configuration and is thereafter transitionable to an expanded configuration, when in its expanded configuration said at least one member defining a blood flow channel and a flow modification region, the blood flow channel being defined by a plurality of coils with at least one of the coils disposed within at least one of the other coils;

said intravascular flow modifier apparatus being deliverable, while in its collapsed substantially linear configuration, through the blood vessel lumen to a location within the blood vessel lumen adjacent to the vessel wall defect and said apparatus being thereafter transitionable to its expanded configuration such that blood flowing through the lumen of the blood vessel may flow through the blood flow channel of the apparatus and the flow modifying region of the apparatus is positioned adjacent to the vessel wall defect so as to modify blood flow from the lumen of the blood vessel into the vessel wall defect.

Claim 120 (Canceled) An apparatus according to Claim 119 wherein the biocompatible member self- expands from its collapsed substantially linear configuration to its expanded configuration.

Claim 121 (Canceled) An apparatus according to Claim 120 wherein the biocompatible member self- expands from its radially collapsed configuration to its radially expanded configuration.

Claim 122 (Canceled) An apparatus according to Claim 119 wherein the biocompatible member comprises a helical coil.

Claim 123 (Canceled) An apparatus according to Claim 119 wherein the biocompatible member comprises an outer layer and an inner layer.

Claim 124 (Canceled) An apparatus according to Claim 123 wherein the outer layer and the inner layer are formed of a continuous strand.

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Claim 125 (Canceled) An apparatus according to Claim 119 wherein the biocompatible member is formed of a shape memory alloy.

Claim 126 (Canceled) An apparatus according to Claim 120 wherein the biocompatible member is formed of a shape memory alloy.

Claim 127 (Canceled) A method for treating a defect in a wall of a blood vessel that has a lumen and a wall, the method comprising the steps of:

- A. providing an apparatus that i) is initially disposable in a collapsed substantially linear configuration and is thereafter transitionable to an expanded configuration and ii) when in its expanded configuration comprises a blood flow channel and a flow modification region, the blood flow channel being defined by a plurality of coils with at least one of the coils disposed within at least one of the other coils;
- B. positioning the apparatus, while in its collapsed configuration, within the lumen of the blood vessel adjacent to the defect;
- C. positioning and expanding the apparatus to its expanded configuration such that i) the apparatus engages the wall of the blood vessel to hold the apparatus in a substantially stationary position within the blood vessel lumen, ii) blood flowing through the blood vessel lumen passes through the blood flow channel of the apparatus and iii) the flow modifying region of the apparatus is positioned relative to the defect to divert blood flow from the defect.

Claim 128 (Canceled) A method according to Claim 127 wherein the vessel wall defect is an aneurysm, Step B comprises positioning the apparatus within the blood vessel lumen adjacent to the aneurysm and Step C comprises positioning and expanding the apparatus such that the apparatus modifies blood flow in a way that strengthens the blood vessel with the aneurysm.

Claim 129 (Canceled) A method according to Claim 128 wherein the aneurysm is a wide mouthed aneurysm and Step C comprises positioning and expanding the apparatus such that the flow modifying region is next to the mouth of the aneurysm.

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Claim 130 (Canceled) A method according to Claim 128 wherein the aneurysm is a cerebral aneurysm.

Claim 131 (Canceled) A system for implantation of an intravascular member within the lumen of a blood vessel, said system comprising:

an elongate, flexible delivery catheter having a distal end, a lumen extending longitudinally therethrough and terminating in a distal end opening, said delivery catheter being advanceable the blood vessel lumen wherein the intravascular member is to be implanted;

an intravascular member which has a collapsed configuration and an expanded configuration wherein it defines a flow channel therethrough, said intravascular member being disposed within the lumen of the delivery catheter while in its collapsed configuration;

an advancer apparatus for advancing the intravascular member out of the distal end opening lumen of the third catheter, said intravascular member being connected to the advancer apparatus by way of a releasable connection,

said advancer apparatus being useable to advance the intravascular member out of the distal end opening of the catheter such that the intravascular member will transition to its expanded configuration within the blood vessel lumen such that blood flowing through the blood vessel lumen will flow through the flow channel of the intravascular member, while the intravascular member remains connected to the advancer apparatus by way of said releasable connection, said releasable connection being thereafter volitionally severable such that the delivery catheter and advancer apparatus may be removed from the blood vessel lumen leaving the expanded intravascular member implanted in said blood vessel lumen.

Claim 132 (Canceled) A system according to Claim 131 wherein the intravascular member comprises a strand that is substantially linear when said collapsed configuration and substantially curvilinear when in said expanded configuration.

Claim 133 (Canceled) A system according to Claim 132 wherein the strand forms a helix when in said expanded configuration.

Claim 134 (Canceled) A system according to Claim 131 further comprising apparatus for releasing the releasable connection.

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Claim 135 (Canceled) A system according to Claim 134 wherein the apparatus for releasing the releasable connection comprises a ball and claw.

Claim 136 (Canceled) A system according to Claim 134 wherein the releasable connection is releasable by being cut and wherein the apparatus for releasing the releasable connection comprises apparatus for cutting the releasable connection.

Claim 137 (Canceled) A system according to Claim 134 wherein the releasable connection is releasable in response to an electrical discharge and wherein the apparatus for releasing the releasable connection comprises apparatus to delivering an electrical discharge.

Claim 138 (Canceled) A method for treating a mammalian patient who has a defect in the wall of a blood vessel that has a lumen and a wall, said method comprising the steps of:

- A. providing a system which comprises; i) a delivery catheter that has a distal end, a lumen that extends longitudinally therethrough and terminates in a distal end opening, ii) an intravascular member which has a collapsed configuration and an expanded configuration wherein it assumes a generally tubular configuration defining a flow channel therethrough, said intravascular member being disposed within the lumen of the delivery catheter while in its collapsed configuration and iii) an advancer apparatus for advancing the intravascular member out of the distal end opening lumen of the third catheter, said intravascular member being connected to the advancer apparatus by way of a releasable connection;
- B. positioning the delivery catheter within the blood vessel such that its distal end opening is near the defect in the wall of the blood vessel;
- D. using the advancer apparatus to advance the intravascular member out of the distal end opening of the delivery catheter such that the intravascular member will transition to its expanded configuration within the blood vessel lumen adjacent to the defect and engage the wall of the blood vessel so as to be held in substantially fixed position within the vessel lumen adjacent to the vessel wall defect and so that blood flows through the flow channel of the intravascular member when it is positioned in the blood vessel; and,
- D. releasing the releasable connection and removing the delivery catheter, thereby leaving the expanded intravascular member implanted within the blood vessel lumen adjacent to the defect.

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Claim 139 (Canceled) A method according to Claim 138 wherein the performance of Steps B and C comprises:

placing a first catheter at a first position within the patient's vasculature;

advancing a second catheter through the lumen of the first catheter and to a second position within the patient's vasculature;

advancing the delivery catheter through the lumen of the second catheter to a third position within the patient's vasculature adjacent the vessel wall defect; and

while the first, second and third catheters are in their respective first, second and third positions, advancing the intravascular member out of the lumen of the third catheter such that the intravascular member assumes its radially expanded configuration.

Claim 140 (Canceled) A method according to Claim 138 further comprising the steps of:

E. providing an embolus member sized to fit within the vessel wall defect; and,

F. positioning the embolus member within the vessel wall defect such that the intravascular member retains the embolus member within the vessel wall defect.

Claim 141 (Canceled) A method according to Claim 140 wherein Step F is performed after Step C.

Claim 142 (Canceled) A method according to Claim 140 wherein Step F is performed before Step C.

Claim 143 (Canceled) A method according to Claim 141 wherein Step F comprises:

- i positioning a delivery catheter having a distal end within the intravascular member after it has been radially expanded in Step E;
- ii causing the distal end of the delivery catheter to advance through a portion of the intravascular member and into the vessel wall defect;
- iii delivering the embolus member out of the distal end of the delivery catheter and into the vessel wall defect; and,
- iv removing the delivery catheter, leaving the embolus member within the vessel wall defect with the intravascular member preventing the embolus

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member from escaping from the vessel wall defect into the lumen of the blood vessel.

Claim 144 (Canceled) A method according to Claim 140 wherein the vessel wall defect is an aneurysm and wherein Step F comprises positioning the embolus member within the aneurysm.

Claim 145 (Canceled) A method according to Claim 144 wherein the aneurysm is a wide mouthed aneurysm and wherein Step F comprises delivering the embolus member through the mouth of the aneurysm and into the aneurysm sac.

Claim 146. (Canceled) A method according to Claim 140 wherein the embolic member delivered in Step F comprises a thrombogenic member.

Claim 147. (Previously Added) A method for treating a mammalian patient who has a defect in the wall of a blood vessel that has a true lumen and a wall, said method comprising the steps of:

A. providing a system that comprises; i) a delivery catheter; ii) an intravascular member that assumes a collapsed configuration when positioned within the delivery catheter and an expanded configuration when advanced out of the delivery catheter ~~that has a collapsed configuration wherein it is positionable within the delivery catheter and an expanded configuration a it is generally tubular in configuration and defines a hollow flow channel therethrough,~~ and iii) an advancer for advancing the intravascular member out of the delivery catheter,

said intravascular member being connected to the advancer by way of a releasable connection, said releasable connection being volitionally releasable without requiring rotation of the advancer;

said intravascular member being in the form of an elongate strand when in its collapsed configuration; and

said elongate strand assuming a generally tubular shape having a hollow flow channel therethrough when the intravascular member is in its expanded configuration;

B. positioning the delivery catheter within the true lumen of the blood vessel near the defect;

C. using the advancer apparatus to advance the intravascular member out of the delivery catheter and causing the intravascular member to transition to its expanded configuration within the true lumen of the blood vessel, adjacent to the defect, such that, i) the intravascular member engages the wall of the blood vessel so as to be held in substantially fixed position within the true lumen of the blood vessel, ii) no substantial

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portion of the intravascular member extends into the defect and iii) blood flowing through the true lumen of the blood vessel lumen passes through the flow channel of the intravascular member; and,

D. releasing the releasable connection and removing the delivery catheter, thereby leaving the expanded intravascular member implanted within the true lumen of the blood vessel adjacent to the defect

E. providing an embolus member sized to fit within the vessel wall defect; and

F. positioning the embolus member within the vessel wall defect such that the intravascular member retains the embolus member within the vessel wall defect.

Claim 148 (Previously Added) A method according to Claim 147 wherein the performance of Steps B and C comprises:

placing a first catheter at a first position within the patient's vasculature;

advancing a second catheter through the lumen of the first catheter and to a second position within the patient's vasculature;

advancing the delivery catheter through the lumen of the second catheter to a third position within the true lumen of the blood vessel, adjacent to the vessel wall defect; and

while the first, second and third catheters are in their respective first, second and third positions, advancing the intravascular member out of the lumen of the third catheter such that the intravascular member assumes its expanded configuration within the true lumen of the blood vessel.

Claim 149 (Cancelled) A method according to Claim 147 further comprising the steps of:

E. providing an embolus member sized to fit within the vessel wall defect; and,

F. positioning the embolus member within the vessel wall defect such that the intravascular member retains the embolus member within the vessel wall defect.

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Claim 150 (Amended) A method according to Claim ~~149~~ 147 wherein Step F is performed after Step C.

Claim 151 (Amended) A method according to Claim ~~149~~ 147 wherein Step F is performed before Step C.

Claim 152 (Amended) A method according to Claim ~~149~~ 147 wherein Step F comprises:

- i positioning a delivery catheter having a distal end within the intravascular member after completion of Step C;
- ii causing the distal end of the delivery catheter to advance through a portion of the intravascular member and into the vessel wall defect;
- iii delivering the embolus member out of the distal end of the delivery catheter and into the vessel wall defect; and,
- iv removing the delivery catheter, leaving the embolus member within the vessel wall defect with the intravascular member preventing the embolus member from escaping from the vessel wall defect into the lumen of the blood vessel.

Claim 153 (Amended) A method according to Claim ~~152~~ 147 wherein the vessel wall defect is an aneurysm and wherein Step F comprises positioning the embolus member within the interior of the aneurysm and outside of the true lumen of the blood vessel.

Claim 154 (Amended) A method according to Claim ~~152~~ 147 wherein the aneurysm is a wide mouthed aneurysm and wherein Step F comprises delivering the embolus member through the mouth of the aneurysm and into the aneurysm sac.

Claim 155 (Amended) A method according to Claim ~~152~~ 147 wherein at least a portion of the embolic member delivered in Step F is thrombogenic.

Claim 156 (Amended) A system for treating an aneurysm or other defect in the wall ~~implantation of an intravascular member within the true lumen~~ of a blood vessel that has a wall and a true lumen through which blood normally flows, said system comprising:

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an elongate, flexible delivery catheter having a lumen extending longitudinally therethrough and a distal end opening, said delivery catheter being advanceable in to the true lumen of a blood vessel ~~wherein the intravascular member is to be implanted;~~

an intravascular member that has a collapsed configuration wherein it is in the form of an elongate strand member that is positionable within the delivery catheter and an expanded configuration wherein it is the elongate strand member assumes a generally tubular shape that in configuration and defines a hollow flow channel therethrough, and

an advancer for advancing the intravascular member out of the delivery catheter, said intravascular member being connected to the advancer by way of a releasable connection, said releasable connection being volitionally releasable without requiring rotation of the advancer, and

an embolic member that is implantable within the aneurysm or other defect in the wall of the blood vessel;

said advancer being useable to advance the intravascular member out of the distal end opening of the delivery catheter such that the intravascular member expands to its expanded configuration within the true lumen of the blood vessel in an orientation that is substantially coaxial with the advancer and such that blood flowing through the blood vessel lumen will flow through the flow channel of the intravascular member, while the intravascular member remains connected to the advancer apparatus by way of said releasable connection;

said releasable connection being thereafter volitionally severable such that the delivery catheter and advancer apparatus may be removed from the blood vessel lumen leaving the expanded intravascular member implanted in said blood vessel lumen

said embolic member being implantable within the aneurysm or other defect such that the intravascular member prevents the embolic member from escaping from the aneurysm or other defect and into the true lumen of the blood vessel.

Claim 157 (Cancelled) A system according to Claim 156 wherein the intravascular member comprises a strand that is substantially linear when said collapsed configuration and substantially curvilinear when in said expanded configuration.

Claim 158 (Amended) A system according to Claim 157 wherein the elongate strand member forms [[a]] at least one helix when in said expanded configuration.

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Claim 159 (Previously Added) A system according to Claim 156 further comprising apparatus for releasing the releasable connection.

Claim 160 (Cancelled) A system according to Claim 156 wherein the releasable connection comprises a ball and claw.

Claim 161 (Cancelled) A system according to Claim 156 wherein the releasable connection is releasable by being cut and wherein the apparatus for releasing the releasable connection comprises apparatus for cutting the releasable connection.

Claim 162 (Amended) A system according to Claim 156 wherein the releasable connection is releasable in response to an electrical current and ~~wherein the apparatus for releasing the releasable connection comprises apparatus for delivering electrical current.~~

Claim 163 (New) A method according to Claim 147 wherein, after the intravascular member has been advanced out of the catheter and deployed in its expanded configuration, the intravascular member is retractable back to its collapsed configuration within the catheter until such time as the releasable connection has been volitionally released.

Claim 164 (New) A method according to Claim 163 further comprising the step of:
after the intravascular member has been advanced out of the catheter and deployed in its expanded configuration but before volitionally releasing the releasable connection, retracting the intravascular member back to its collapsed configuration within the catheter.

Claim 165 (New) A system according to Claim 156 wherein, after the intravascular member has been advanced out of the catheter and deployed in its expanded configuration, the intravascular member is retractable back to its collapsed configuration within the catheter until such time as the releasable connection has been volitionally released.

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